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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/666,440

09/19/2003

Timothy John Henkel

9404.0005-02

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03/04/2008

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EXAMINER

YOUNG, MICAH PAUL

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

03/04/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.



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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/666,440
Filing Date: September 19, 2003
Appellant(s): HENKEL, TIMOTHY JOHN

Jessica H. Roark
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 12/14/07 appealing from the Office action mailed 7/12/07.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

File et al, "Gemifloxacin versus amoxycillin/clavulanate in the treatment of acute exacerbation of chronic bronchitis". The 070 Clinical Study Group. Journal of Chemotherapy, 12(4) (August 2000), pp. 314-325

WO 98/42705 A1

KIM et al

10-1998

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

1. Claims 1, 4-8, 11-26, 34 and 35 are rejected under 35 U.S.C. 102(a) as being anticipated by File et al (*Gemifloxacin versus amoxicillin/clavulanate in the treatment of acute exacerbation of chronic bronchitis. The 070 Clinical Study group*. J. Chemotherapy; August 2000; 12(4): 314-25). The claims are drawn to a method of reducing the recurrence of acute exacerbation of chronic bronchitis (AECB) in a patient in need thereof with an effective dosage of gemifloxacin.
2. The reference discloses a study where gemifloxacin is compared to amoxicillin/clavulanate in its treatment of AECB (abstract). The patients participating in the study have been suffering from chronic bronchitis for more two (2) consecutive years, and most days in a period of three (3) months (pg. 315). Gemifloxacin is given orally at 320 mg once daily for five (5) days (pg. 316). Patients were assessed at a follow-up where symptoms and bacterial activity were monitored and recorded (pg 316). The results of the study show that

gemifloxacin is just as effective a treatment regimen for AECD as amoxicillin/clavulanate (pg. 323). These disclosures render the claims anticipated.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
3. Claims 2, 3, 9, 10, 27-33, 36-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of File et al (*Gemifloxacin versus amoxicillin/clavulanate in the treatment of acute exacerbation of chronic bronchitis. The 070 Clinical Study group*. J. Chemotherapy; August 2000; 12(4): 314-25) and Kim et al (WO 98/42705). The claims are drawn to a method of reducing the occurrences of AECD by administering gemifloxacin salts.
4. As discussed above the File study discloses a treatment for the reduction of AECD occurrences by administering gemifloxacin. However the study is silent to the particular salts of

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the drug available for use. Kim however discloses these compounds and suggests their use in the treatment of respiratory infections (abstract). The reference discloses various derivatives and salts including mesylate and sesquihydrate salts (pg 10, lin. 6- pg 11 lin 3). It is well within the level of skill in the art to substitute salts of known compounds into varying treatment regimens, in order to account for difference in solubility or other treatment variables. These substitutions would be obvious to one of ordinary skill in the art.

5. Regarding claims drawn to the specific follow-up regimen it is the position of the Examiner that such limitations would be obvious to one of ordinary skill in the art of patient care. The File study teaches that a long-term follow-up procedure is best for monitoring patients; however the specific intervals would be well within the level of skill in the art. Barring a showing of unexpected results regarding the particular follow-up procedures, it is the position of the Examiner that these limitations do not impart patentability.

6. With these things in mind, one of ordinary skill in the art would have been motivated to substitute the salts of Kim into the treatment regimen taught by File in order to account for changes in solubility during the treatment regimen. The artisan of ordinary skill would have been able to make these substitutions with an expected result of a method of reducing AECB occurrences in patients in need thereof.

(10) Response to Argument

1. Applicant argues that:

- a. The File reference is not available under any 10 statute since it was not available to the public prior to the priority date of the instant application.

- b. Since the File reference is not available under any 102 statute it in turn is not available to be combined with Kim to obviate the instant claims.

2. Regarding argument a, it remains the position of the Examiner that the File reference would have been available well before the priority date of the instant invention and anticipates the instant invention. As previously argued, the File patent has a publication date of August 2000, and as indicted by the publisher the latest the reference would have been mailed or emailed to subscribers would have been September 1, 2000. With the availability of next day mailings and the instant access of electronic mail the reference would have been electronically available to subscribers to the Journal and artisans of ordinary skill on September 1, 2000. With September 1, 2000 being a Friday the reference would have been available to subscribers via postal services no later than September 4 or 5, 2000. Even at the latest the reference would have been available as prior art the least 10 days prior to the priority date of the instant invention. Further Applicant continues to argue that the date stamp of the NIH library as proof that the reference was not available to the public; however the NIH library is not the only library available to the public. There are hundreds of Colleges and universities along with medical schools with up to date library services. It is the position of the Examiner that the articles would have been available at any number of these publicly available institutions. As stated in MPEP 2128; A reference is proven to be a "printed publication" "upon a satisfactory showing that such document has been disseminated or otherwise made available to the extent that persons interested and ordinarily skilled in the subject matter or art, exercising reasonable diligence, can locate it." In re Wyer, 655 F.2d 221, 210 USPQ 790 (CCPA 1981) (quoting I.C.E. Corp. v. Armco Steel Corp., 250 F. Supp. 738, 743, 148 USPQ 537, 540 (SDNY 1966)). In accordance with this citation, an email

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from the publisher of the article to subscribers (those of ordinary skill in the art with interest in the subject matter would constitute dissemination of the article making the File reference available as prior art.

3. Regarding argument b., since the reference would have been available as prior art, it would have been available to combine with the Kim patent in order to obviate the instant claims. The file patent teaches a method of treating AECB with gemifloxacin. The reference is silent to the specific salts of the instant claims' however these salts are well known in the art as seen in the Kim patent. The Kim patent discloses a treatment for respiratory infections with gemifloxacin salts such as mesylate and sesquihydrate salts. The claims recite that follow-up appointments would be necessary in the treatment method. The File patent teaches that long term-term follow up procedures are best monitoring patients. These specific patient maintenance procedures would be obvious to one of ordinary skill in the art and would have been in view of the File and Kim disclosures. For these reasons the claims remain obviated by the combination of the File and Kim references.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Micah-Paul Young/

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